

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION FOR

**BONE ANCHOR AND DEPLOYMENT DEVICE THEREFOR**

*Inventors:*

Mark A. Johanson  
a citizen of the United States residing at  
5 Harvest Lane, Littleton, MA

John Rice  
a citizen of the United States residing at  
31 Red Rail Farm Lane, Lincoln, MA

Rickey Hart  
a citizen of the United States residing at  
11 Hillside Road, Plainville, MA

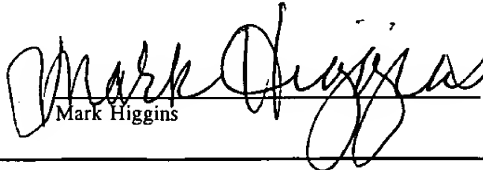
James Nicholson  
a citizen of the United States residing at  
14 Meadowdam Road, Lincoln, MA

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and is addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on the date indicated below.

Express Mailing Label No. EI985602710US

May 28, 1998

Date

  
Mark Higgins

## REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of priority of and is a continuation-in-part of U.S. Application Serial No. 08/595,772, filed on February 2, 1996 (Attorney Docket: 0383311-0040) and of Application Serial No. 08/814,149, filed on March 10, 1997 (Attorney Docket: 0383311-0070) and, thereby, of U.S. Application Serial No. 08/163,130 (now U.S. Patent No. 5,725,529) filed on December 6, 1993 (Attorney Docket: 0383311-0019) and, thereby, of U.S. Application Serial No. 08/765,445 (now U.S. Patent No. 5,268,001) filed on September 25, 1991 (Attorney Docket: 0383311-0018) and, thereby, of U.S. Application Serial No. 08/588,025 (now abandoned) filed on September 25, 1990 (Attorney Docket: 0383311-0043).

*Handwritten notes:*  
Now U.S. PAT. No. 5,768,044  
Now U.S. PAT. No. 5,911,721  
07/205,445  
07/588,025

## BACKGROUND OF THE INVENTION

The present invention is directed to a bone anchor for attaching tissue to bone, and to a device for deploying such an anchor in bone. More specifically, the invention is directed to a bone anchor which employs a "floating" washer that conforms to the angle of the bone surface to hold tissue in place, and to a deployment device having a plunger-like configuration that facilitates deployment of such an anchor.

Soft tissue, such as tendon, may become detached from a patient's bone as a result of injury or a medical procedure. In either case, the tissue must be re-attached in order to permit healing. Medical devices used to perform this function are known as bone anchors.

Traditionally, bone anchors were merely tacks or nails that were hammered through a patient's soft tissue and directly into the patient's bone. Anchors of this type, however, had many deficiencies. For example, they were prone to coming out of the bone, particularly in cases where patients were relatively active. In addition, because the

anchors were hammered directly into the bone, deployment was difficult and could sometimes result in hairline fractures.

5 In recent times, more sophisticated bone anchors have been developed which alleviate some of the problems mentioned above. For example, many bone anchors now include prongs or something similar, which reduce the chances that the anchor will dislodge from the bone. Likewise, bone anchors have now been developed which can be inserted into pre-formed holes in bone, rather than being hammered.

10 When affixing tissue directly to bone, it is often desirable to deploy the bone anchor at an angle that is normal to the bone surface. If this is not done, then sufficient contact may not be achieved with the surrounding tissue to hold the tissue in place. Understandably, achieving such placement can be difficult when the anchors are placed endoscopically.

15 In addition to the foregoing, the force required to deploy a conventional bone anchor often makes deployment problematic. Driving a tack or nail-like anchor into bone, for example, is difficult if the surgeon does not have adequate leverage on the bone to counterbalance the force of impact.

20 Thus, there exists a need for a bone anchor which does not need to be deployed at a precise angle in order to attach tissue to bone reliably, and a device for deploying such an anchor which does not require a surgeon to impart substantial counterforce against the device during bone anchor deployment.

25 In view of the foregoing, an object of the invention is to provide improved bone anchors and methods for deployment thereof. A related object is to provide improved devices for deploying such anchors.

A further object is to provide anchors that attach tissue firmly and reliably, regardless of the angle of deployment.

A still further object is to provide anchors, methods and devices for deployment  
5 thereof suitable for use in endoscopic procedures.

Yet a still further object is to provide such anchors, methods and devices that can be deployed easily and without application of unnecessary leverage or counterforces.

05036503-052393  
060250-00598060

## SUMMARY OF THE INVENTION

The present invention addresses the foregoing objects by providing a rivet-like bone anchor having a floating washer at its head that can adapt to an angled bone surface and, thereby, better secure a tissue thereto. The invention also provides a deployment tool that permits the anchor to be deployed without application of unnecessary counterforce.

Thus, according to one aspect, the present invention is a bone anchor which includes a rivet, an expandable sleeve, and a washer. The rivet includes a head and an elongate body having proximal and distal ends, the head being mounted on the proximal end of the elongate body. The expandable sleeve has an inner bore adapted to receive the rivet body. The washer "floats" at a proximal end of the sleeve. As the rivet is inserted into sleeve, the sleeve expands into an interference fit with the bone. The head of the rivet, moreover, forces the floating washer into contact with the tissue at an angle that conforms to that of the underlying bone surface.

In other aspects of the invention, an external surface of the expandable sleeve and/or the rivet has one or more annular ribs, threads or protrusions. These increase the strength of the interference fits between the rivet and the sleeve, as well as between the sleeve and the bone, thereby reducing the chances that the anchor will dislodge. The washer can likewise include ridges, teeth or other protrusions that enhance fixation of the tissue upon deployment.

In still other aspects of the invention, the bone anchor includes a housing which is frangibly coupled to the expandable sleeve via breakable flanges. The housing, which can be used to affix the anchor to the delivery device, can also protect and store the rivet prior to deployment. During deployment, the head of the rivet breaks the flanges of the housing, thereby freeing the housing from the anchor.

According to another aspect, the present invention provides an apparatus for deploying a bone anchor of the type described above. The apparatus includes an outer tube, the distal end of which can hold the anchor housing, e.g., via a screw fit. A rod, which is slidably disposed within the bore of the tube, can be used to push the rivet into the expandable sleeve so that the sleeve expands into the bone, so that the floating washer is forced into position against the bone surface, and so that anchor is broken away from the housing. This can be effected, for example, by squeezing the proximal ends of the outer tube and the rod together, e.g., in the manner that the end of a syringe is squeezed.

By virtue of this design, the counterforce which a surgeon must impart to the apparatus during bone anchor deployment is eliminated. More specifically, because the outer tube is coupled to the expandable sleeve and because the rod pushes on the rivet, there are no net forces that must be counterbalanced during at least the initial stage of deployment.

According to another aspect, the present invention is a method of deploying a bone anchor of the type described above using a deployment device of the type described above. The method includes pulling the tissue into position over the bone with a guide wire, e.g., a pin or K-wire, and drilling a hole in the bone, e.g., with a drill bit fitted over the end of the guide wire. With the guide wire holding the tissue in place over the bone hole, the bone anchor is then threaded down the wire and into position for deployment (e.g., with the sleeve in the bone hole and the floating washer resting against the tissue and bone surface). The deployment device, which is preferably threaded to the anchor, is simultaneously slid into position for deployment.

According to yet another aspect of the invention, the tissue is pierced and pulled into position over a predrilled bone hole via a guide or probe integral to, and extending from, the distal end of the outer tube. With the guide or probe holding the tissue in place over the bone hole, the bone anchor is passed through the outer tube, threaded through the tissue and into the bone hole.

Still further aspects of the invention provide for securing the sleeve into the bone hole by threading it through clockwise (or counter-clockwise) rotation of the outer tube.

5 The rivet is deployed by squeezing the proximal end of the outer tube and inner rod together in a syringe-like motion, or put another way, by applying downward force to the inner rod and upward force to the outer tube thereby forcing the rivet out of the housing and into the expandable sleeve. Continued application of these forces, at least partially sets the floating washer in conformity to the angle of the underlying bone surface and causes the frangible flanges to break, thereby freeing the housing from the sleeve. Once the anchor is at least partially deployed, the deployment device and attached housing (sans anchor) are removed from the site. The inner tube of the deployment device is then rethreaded down the K-wire so that its distal end re-abuts the head of the rivet. By applying force (e.g., tapping) to the proximal end of the inner rod, the rivet is fully set, fully fixing the washer at the angle of the underlying bone surface.

15

A more complete understanding of the invention can be obtained by reference to the following detailed description of the preferred embodiments thereof in connection with the attached drawings.

[illegible]

5

10

15

20

文

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figures 1 and 2 are close-up, cut-away views of a bone anchor according to the present invention. As shown in Figure 1, bone anchor 1 includes housing 2, expandable sleeve 4, rivet 6, floating washer 7, breakable flanges 9, and threading 10. In preferred embodiments of the invention, some or all of these components are made of a bioabsorbable material which dissolves in a patient's body over a period of time leaving little or no trace. Alternatively, bone anchor 1 may be made of other biocompatible materials, such as conventional plastics or the like.

Rivet 6 is comprised of head 11, elongate body 12, tapered tip 14, and a centerbore (not shown) running therethrough. Head 11 is located at the proximal end of rivet 6 and has a diameter which is greater than that of either elongate body 12 or tapered tip 14. Head 11 also includes undersurface 15. Undersurface 15 can be formed with a spherical radius or, alternatively, angled relative to a longitudinal axis of the elongate body. Thus, as shown in the illustration, the undersurface is angled relative to plane 16 which, as shown in Figure 1, bisects elongate body 12 at a right angle. Preferably, undersurface 15 is angled at 45 degrees; although other angles may be used. Elongate body 12 includes annular ribs 8 on an outer surface thereof, which are adapted to aid in maintaining rivet 6 in sleeve 4. It should be noted, however, that elongate body 12 need not include annular ribs in order to perform its function. Tapered tip 14 is located at the distal end of rivet 6, and has a diameter which decreases gradually from the diameter of elongate body 12 to less than that of inner bore 19 of expandable sleeve 4.

Prior to deployment of bone anchor 1, rivet 6 is housed in housing 2, as shown in Figure 1. Housing 2 is preferably cylindrical in shape and includes threading 10 at first open end 20. Threading 10 is adapted to connect bone anchor 1 to a bone anchor delivery device, such as that described in detail below. Housing 2 is integrally coupled with expandable sleeve 4 via flanges 9, which are sized to break in response to either

downward or upward pressure against head 11 so as to disconnect (i.e., free) housing 2 from expandable sleeve 4.

Expandable sleeve 4 includes inner bore 19, as noted above, and is fabricated of a material which is capable of expanding into an interference fit with a bone hole. Inner bore 19 has a diameter that is less than the diameter of elongate body 12, but which is greater than or equal to a diameter of tapered tip 14. As a result of these dimensions, expandable sleeve 4 is able to receive rivet 6, distal-end-first. As described in more detail below, expandable sleeve 4 expands as elongate body 12 moves into expandable sleeve 4, eventually resulting in the arrangement shown in Figure 2, in which expandable sleeve 4 is fully expanded. When bone anchor 1 is deployed in a hole in a bone, this expansion results in an interference fit between expandable sleeve 4 and the bone. To aid in expansion, expandable sleeve 4 also may include radial or longitudinal slots (not shown) which runs all or part-way along expandable sleeve 4. In addition, a membrane may also be included on the slot, which permits expansion while, at the same time, guarding against breakage of expandable sleeve 4.

The outer surface of expandable sleeve 4 includes annular ribs or threads 17 along at least a portion thereof. Annular ribs or threads 17 contact sides of a bone hole into which bone anchor 1 is implanted and, when expandable sleeve 4 is expanded, assist in maintaining bone anchor 1 in the bone. This feature of the invention is described in more detail below.

Disposed around the outer surface of expandable sleeve 4 is washer 7. Washer 7 may be of any shape, i.e., it may be elliptical, circular, etc., and may include ridges or other protrusions on its undersurface for improved contact with tissue or bone. When bone anchor 1 is not deployed in a bone, washer 7 "floats", meaning that it is capable of at least longitudinal motion and limited angular motion relative to expandable sleeve 4. Washer 7 may be capable of lateral motion relative to expandable sleeve 4 as well. Thus, referring to Figure 1, washer 7 is capable of longitudinal motion along line 22 and

of angular motion at, e.g., angles 23 and 24. This longitudinal motion and angular rotation is possible when expandable sleeve 4 is fully unexpanded and, preferably, also when it is fully expanded. Washer 7 also has a top surface 25 which abuts with undersurface 15 of rivet 6, and which may or may not be angled or radiused relative thereto. In the embodiment shown in Figures 1 and 2, top surface 25 of washer 7 is not angled or radiused.

Bone anchor 1 is deployed into a hole in a bone using a plunger-like deployment device, such as that shown in Figure 3. As shown in Figure 3, bone anchor deployment device 26 is comprised of tube 27 and rod 29. These components may be fabricated of any material; although stainless steel is used in the preferred embodiment. Tube 27, which is shown in Figure 4, has a bore (not shown) therethrough for receiving rod 29. At distal end 30, the inner surface of tube 27 includes threading (not shown). This threading is adapted to mate with threading of a bone anchor, such as bone anchor 1, in order to hold the housing of the bone anchor substantially immobile during deployment. Tube 27 also includes "T"-shaped handle 31 at its proximal end. Handle 31 interacts with knob 32 of rod 29 so as to limit the motion of rod 29 relative to tube 27.

In this regard, rod 29, which is shown in Figure 5, is removably disposed within the bore of tube 27 and is slidable therein. That is, rod 29 can be removed from tube 27 merely by sliding rod 29 out of tube 27. In addition, rod 29 is capable of sliding within tube 27 such that distal end 34 of rod 29 extends out from tube 27 (see Figure 3). This feature of rod 29 makes it possible for rod 29 to move within at least a portion of the housing of a bone anchor connected to tube 27, as described in more detail below. As noted above, rod 29 also includes knob 32, which contacts handle 31 of tube 27 in order to limit the motion of distal end 34 relative to tube 27. Finally, rod 29 includes a centerbore (not shown) which is capable of receiving a guide wire, such as a K-wire and/or the like.

Figures 6 through 12 explain operation of both bone anchor 1 and deployment device 26 in the context of deploying a bone anchor into a bone during an endoscopic or other surgical procedure. To initiate such a procedure, a K-wire is inserted through the tissue (e.g., tendon) and into the bone at which a bone anchor is to be deployed. A hole  
5 is then formed in the bone at that location, e.g., via a drill bit or other cutting device disposed at the distal end of the K-wire. In this regard, hole 37 can be formed by any conventional means. In preferred embodiments of the invention, however, a drill bit or other cutting device (not shown) is slid over K-wire 36 so as to secure the drill bit to K-wire 36 in order to drill hole 37. Thereafter, the drill is removed from K-wire 36. In  
10 these embodiments of the invention, a drill guide which is used with such a drill may take the place of the K-wire entirely. The following, however, assumes that a K-wire is used. The result of these steps is shown in Figure 6, namely K-wire 36 in hole 37.

After, before or during formation of hole 37 in bone 39, a bone anchor, such as  
15 that shown in Figure 1, is installed in a bone anchor deployment device, such as that shown in Figure 3. Specifically, with reference to Figure 6, housing 2 of bone anchor 1 is screwed into inner threads of tube 27 on deployment device 26. Once this has been done, bone anchor deployment device 26 and bone anchor 1 are slid over K-wire 36 via respective throughbores of sleeve 4, rivet 6 and rod 29. This is shown in Figure 6.

20 Next, as shown in Figure 7, expandable sleeve 4 on bone anchor 1 is inserted through soft tissue 40 and into hole 37 of bone 39. Since expandable sleeve 4 is not expanded at this stage of the deployment process, little actual pressure is required on the part of the surgeon in order to insert expandable sleeve 4 into hole 37. As shown in  
25 Figure 7, rod 29 may also be moved into contact with rivet 6 at this point by pressing down on knob 32. This pressure may be applied by any means, such as by a surgeon "squeezing" handle 31 and knob 32 together using one hand in a syringe-like manner. Alternatively, hammer blows may be applied to knob 32 while holding tube 27 in place.

09086503-052899  
0602250-80598060

In any event, following insertion of expandable sleeve 4 into hole 37, additional pressure is applied to knob 32 to begin initial deployment of rivet 6 into expandable sleeve 4. Specifically, downward pressure is applied to rivet 6 by sliding rod 29 downwards relative to tube 27 so as to force rod 29 into housing 2 and to force rivet 6 out of housing 2 and into expandable sleeve 4. Since housing 2 is held substantially immobile by tube 27, and since housing 2 is connected to sleeve 4, the process of deploying rivet 6 has little or no effect on the bone. That is, the downward force applied to rivet 6 is not significantly imparted to bone 39 because rivet 6 moves within housing 2 and sleeve 4, both of which are held in place by tube 27. As a result, bone 39 moves little during initial deployment of rivet 6.

As shown in Figures 8 and 9, as rivet 6 is deployed into expandable sleeve 4, expandable sleeve 4 expands within hole 37. This expansion results in an interference fit between bone anchor 1 (meaning rivet 6 and expandable sleeve 4) and bone 39. Annular ribs 17 on expandable sleeve 4 strengthen this interference fit by coming into relatively tight contact with the sides of hole 37. In addition, annular ribs 18 on rivet 6 also enhance the reliability of the interference fit by reducing the chances that rivet 6 will come out of expandable sleeve 4.

The initial deployment process depicted in Figures 6 through 9 causes rivet 6 to be moved substantially, but not completely, into hole 37 of bone 39. That is, as shown in Figure 9, following initial deployment, there is still a space 42 between rivet 6 and a bottom of hole 37. Moreover, as also shown in Figure 9, following initial deployment, washer 7 is not firmly sandwiched between head 11 of rivet 6 and tissue 40 on bone 39. Since washer 7 is preferably firmly sandwiched between head 11 and tissue 40 in order for bone anchor 1 to function properly, additional steps are performed in order to complete deployment.

Specifically, in order to complete deployment of bone anchor 1, deployment device 26 must be removed from K-wire 36 and housing 2 must be disconnected from

expandable sleeve 4. One advantage of the present invention is that these actions may be performed concurrently. More specifically, as noted above, bone anchor 1 includes flanges 9 which break when sufficient force is applied thereto. In the present invention, this force may comprise either contact with head 11 during downward movement of rivet 6 into expandable sleeve 4, or contact with head 11 during upward movement of tube 27. In this regard, to break flanges 9 during upward movement of tube 27, downward pressure is retained on rod 29 and upward pressure is applied to tube 27.

In any event, as shown in Figure 10, once flanges 9 break, deployment device 26, with housing 2 still attached thereto, can be slid off of K-wire 36, leaving rivet 6, washer 7, and expandable sleeve 4 within bone 39. Final deployment then can begin by disconnecting rod 29 from tube 27 (i.e., by sliding rod 29 out of tube 27) and sliding rod 29 back over K-wire 36, as shown in Figure 11. Washer 7 is then set in place by applying a force to knob 32 of rod 29 by way of hammer blows or the like. Because this additional force can be applied via hammer blows or the like, the need for a surgeon to exert counterforce during final deployment is reduced.

The additional force applied above causes rivet 6 to move substantially all the way into hole 37, thereby resulting in firm contact between head 11 and washer 7. As a result of this contact, head 11 forces washer 7 against tissue 40 so that washer 7 is firmly sandwiched between head 11 and tissue 40. In this regard, since washer 7 floats relative to bone surface, head 11 forces washer 7 against tissue 40 so that washer 7 is substantially parallel to a surface of bone 39, i.e., so that washer 7 is disposed at an angle that substantially conforms to a surface of the underlying bone (see Figure 12). The angle or radii of the undersurface of head 11 described above facilitates this placement. As a result, washer 7 is able to hold tissue 40 in place. Thus, by using a floating washer in this manner, the invention reduces the need to implant the bone anchor at a precise angle relative to the bone.

The present invention has been described with respect to particular illustrative embodiments. It is to be understood that the invention is not limited to the above-described embodiments and modifications thereto, and that various changes and modifications may be made by those of ordinary skill in the art without departing from  
5 the spirit and scope of the appended claims.

09086503.052899